Remarks

Claims 1, 3, 5-8, 10 and 16 were pending in this application. Claims 17-22 are new; support for these new claims may be found throughout the specification and the claims as originally filed, including at least in Examples 1-4. After entry of this amendment, **Claims 1, 3, 5-8, 10 and 16-22 are pending**.

No new matter is introduced by the foregoing amendments. Consideration and allowance of the pending claims are requested.

Entry of the amendments after final action is appropriate because the amendments are believed to place the claims in a condition for allowance, clarify the issues for an appeal and require no additional search.

Interview with Examiner Kumar

Applicants thank Examiner Kumar for discussing the pending Office action with their undersigned representative on February 20, 2008. During this interview, the status of independent claim 3 was discussed. Applicants' representative asked for clarification regarding claim 3 since the Office action Summary states that it is rejected, but the detailed Office action does not refer it anywhere. Examiner Kumar stated that further investigation was needed to determine the status of claim 3.

Examiner Kumar agreed to consider Applicants arguments and amendments made herein. In particular, Examiner Kumar agreed to review the method claims and composition claims independently and completely. It is believed that this response is prepared in accordance with suggestions made by Examiner Kumar.

Allowance of Claim 3

Applicants believe that claim 3 is allowable. The Office action does not set forth any specific rejections for such claim. As such, no changes have been made to this claim. Applicants request that the Office proceed with the allowance of claim 3 and all claims that depend therefrom (claims 17-19).

As the Office is aware, an examiner "ordinarily should reject each claim on all valid grounds available." M.P.E.P. §707.07(g). Further, an examiner's action should be complete as to all matters. 37 C.F.R. 1.104 and M.P.E.P. §707.07(a). As such, if the Office finds that specific rejections for claim 3 were omitted, Applicants request that prosecution be re-opened, since such rejections should have been made prior to issuing the Final Office action.

Rejections under 35 U.S.C. §102(b)

Claims 1, 5-8, 10 and 16 stand rejected under 35 U.S.C. §102(b), as allegedly anticipated by Alexandrov *et al.* (EP 1033405, Published June 9, 2000; hereinafter Alexandrov *et al.*) taken together with the evidence of Van Winkle *et al.* (US Patent Publication No. US 2005/0257294 A1; hereinafter Van Winkle *et al.*). Applicants respectfully traverse this rejection for at least the following reasons.

As previously presented in the Office Action Response submitted on September 4, 2007:

Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration. *W.L. Gore & Assocs. v. Garlock*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). Further, "anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim." *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481, 485 (Fed. Cir. 1984) (citing *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983)).

Presently, the Office has failed to satisfy the criteria for an anticipation rejection as set forth by *W.L. Gore & Assocs. or Lindemann Maschinenfabrik GMBH*, particularly with regard to the claims now pending in the case. Although the Office cites multiple pages within Alexandrov *et al.* to support the pending rejection, nowhere do Alexandrov *et al.* disclose, suggest or teach "a transgenic plant comprising a plant transformation vector comprising a heterologous constitutive promoter ... [that] provides overexpression of a DRO2 transcript in which said transgenic plant has increased drought tolerance as compared to a non-transgenic control plant," as presently claimed. Further, Alexandrov *et al.* do not disclose each and every element of the claimed invention, particularly not as arranged in the

claim. Therefore, the teachings of Alexandrov *et al.* are insufficient to establish anticipation because each and every element of the claimed invention are not revealed or noted in the reference.

The Office alleges that the property of drought tolerance of a transgenic plant expressing a polynucleotide sequence of SEQ ID NO: 33003 is inherent to the sequence disclosed in the reference. Applicants respectfully disagree. The property of drought tolerance is a product of at least the components of the vector construct (including the nucleotide sequence that encodes the DRO2 polypeptide) utilized by Applicants to transform the transgenic plant. As demonstrated in Examples 1 and 4, **overexpression** of DRO2 transcript results in the drought tolerant phenotype. Applicants have additional data demonstrating these effects and would be pleased to submit them upon the Office's request.

The sequence alone is not sufficient to result in a transgenic plant as presently claimed. This is also supported by the teachings of Harper *et al.* (U.S. Patent No. 7,109,033, as discussed below), in which endogenous expression of a stress-related polynucleotide (*e.g.*, SEQ ID NO: 1986) regulated by its native stress-responsive promoter(s) **did not** result in a drought resistant phenotype (as noted by the Office on page 7 of the May 1, 2007 Office Action). Therefore, the properties of drought resistance are not inherent to the coding sequence alone.

Alexandrov *et al.* also fail to disclose each and every step of the present method claims 3 and 7. For example, nowhere do Alexandrov *et al.* disclose any **method** of increasing drought tolerance in a plant by use of a nucleotide sequence that encodes a DRO2 polypeptide comprising an amino acid sequence having at least 95% sequence identity to the amino acid sequence of SEQ ID NO: 2. Alexandrov *et al.* also do not teach, suggest or disclose a **method** involving the overexpression of a DRO2 transcript to increase drought resistance in a plant or "identifying said transgenic plant with increased drought tolerance by measuring relative water content of said transgenic plant", as presently claimed in claim 3. Thus, the Office has failed to establish anticipation of the current claims because each and every element of the claimed invention is not disclosed in a single reference (*i.e.*, Alexandrov *et al.*).

Additionally, the Office incorrectly relies upon the present disclosure (Van Winkle *et al.*) to establish anticipation based upon inherency for the disclosed **methods**. As established, a new use of a known substance (*e.g.*, a sequence) is patentable subject matter. Therefore, the Office cannot utilize the present disclosure to establish inherent anticipation for at least the **method** claims. Applicants respectfully request that the Office provide statutory authority to the contrary. Since the **use to increase drought resistance in a plant** of a nucleotide sequence that encodes a DRO2 polypeptide comprising an amino acid sequence having at least 95% sequence identity to the amino acid sequence of SEQ ID NO: 2 is not disclosed by Alexandrov *et al.*, anticipation has not been established.

Newly Submitted Arguments:

In addition to the arguments previously set forth (in the September 4, 2007 Office action Response and above), Applicants further stress that Alexandrov *et al.* fail to anticipate the present disclosure because they do not disclose each and every element of the claimed invention, particularly not as arranged in the claim. As stated above, the property of drought tolerance is a product of at least the components of the vector construct (including the nucleotide sequence that encodes the DRO2 polypeptide and the heterologous constitutive promoter) utilized by Applicants to transform the transgenic plant. The sequence alone is not sufficient to result in a transgenic plant as presently claimed (as demonstrated by Harper *et al.*). Nowhere do Alexandrov *et al.* disclose the specific combination of a heterologous constitutive promoter and the nucleotide sequence that encodes the DRO2 polypeptide as presently arranged in Applicants' independent claims 1 and 16. Therefore, the teachings of Alexandrov *et al.* are insufficient to establish anticipation, at least because each and every element of the claimed invention are not disclose as arranged in the presented claims.

In view of the above arguments, and the amendments made herewith, Applicants request withdrawal of the rejections under §102(b).

Rejections under 35 U.S.C. §102(e)

The Office also rejects the claims under §102(e) as being (inherently) anticipated by Harper *et al.* (U.S. Patent No. 7109033) taken together with the evidence of Van Winkle *et al.* (U.S. Patent Publication No. US 2004/0009476 A9). For example, the Office alleges that Harper *et al.* "disclose a

stress (includes drought) tolerant transgenic plant and a method of making said transgenic plant comprising introducing and expressing a polynucleotide sequence of SEQ ID NO: 1986 which has 100% sequence identity to instant SEQ ID NO: 1 which encodes instant SEQ ID NO: 2." (Office Action, page 5). Applicants respectfully disagree.

As previously presented in the Office Action Response submitted on September 4, 2007:

While Applicants agree that Harper *et al.* disclose polynucleotide sequence SEQ ID NO: 1986 which appears to be identical to Applicants' SEQ ID NO: 1, Harper *et al.* do not teach, suggest, or disclose a drought tolerant transgenic plant or a method of its use as presently claimed, at least for the same reasons as discussed in detail above for Alexandrov *et al.* For example, the property of drought tolerance is a product of at least the components of the vector construct (including the nucleotide sequence that encodes the DRO2 polypeptide) utilized to transform the transgenic plant and not just SEQ ID NO: 1986 alone. As previously stated in the Response submitted on May 28, 2007, transcriptional profiling studies performed by Harper *et al.* indicate that levels of transcripts with a polynucleotide sequence of SEQ ID NO: 1986 were not increased in plants treated mannitol (osmotic stress) alone (Tables 11, 12 and 13). In addition, such transcript levels were not reported to be more abundant in plants given a combination of osmotic stress with other stress conditions including cold and mannitol (Tables 15, 16 and 17), salt and mannitol (Tables 21, 22 and 23) or cold, salt and mannitol (Tables 24, 25 and 26). Thus, the gene with SEQ ID NO: 1986 was not observed to be responsive to drought-like stresses (such as mannitol treatment). Furthermore, transcripts of SEQ ID NO: 1986 were not induced by cold alone (Tables 3, 4 and 5), or salt alone (Tables 7, 8 and 9). Therefore, a transgenic plant with SEQ ID NO: 1986 without a vector construct which causes overexpression of such transcript does not result in a drought tolerant transgenic plant as currently claim.

The Office asserts that Harper *et al.* do not suggest or indicate that transgenic expression of nucleotide sequence encoding SEQ ID NO: 1986 under a (*e.g.*, constitutive) promoter would **not** result in a drought tolerant transgenic plant. It is also alleged by the Office that the data presented in Harper *et al.* does not provide evidence **against** the drought tolerant property of the product (SEQ ID NO: 1986). Applicants respectfully but strenuously disagree. Anticipation cannot be established on mere

possibilities or probabilities. Each and every element of the claim must be disclosed in a single reference. As such, the fact that a reference does not teach or suggest that something would not result in a particular invention can not be used to established anticipation. Moreover, the data presented by Harper *et al.* demonstrate that the property of drought tolerance is not observed in the absence of a vector construct including at least the nucleotide sequence as well as a promoter that causes overexpression of the DRO2 transcript (*i.e.*, the studies by Harper *et al.* which included the nucleotide sequence with a native stress promoter did not result in the phenotype being observed). As such, the Office has failed to establish anticipation based upon inherency for the transgenic plant as presently claimed (claims 1 and 16).

Harper *et al.* also fail to disclose each and every step of the presently claimed methods, *e.g.* claims 3 and 7. For example, nowhere do Harper *et al.* disclose any **method of increasing drought tolerance** in a plant by use of a nucleotide sequence that encodes a DRO2 polypeptide comprising an amino acid sequence having at least 95% sequence identity to the amino acid sequence of SEQ ID NO: 2. Harper *et al.* also do not teach, suggest or disclose a method involving the overexpression of a DRO2 transcript to increase drought resistance in a plant, or "identifying said transgenic plant with increased drought tolerance by measuring relative water content of said transgenic plant" as presently required in claim 3. Thus, the Office has failed to establish anticipation for the present method claims 3 and 7 (and those that depend therefrom) because each and every element of the claimed invention is not disclosed in a single reference (*i.e.*, Harper *et al.*).

Newly Submitted Arguments:

In addition to the arguments previously set forth (in the September 4, 2007 Office action Response and above), Applicants wish to further stress that Harper *et al.* fail to anticipate the present disclosure because they do not disclose each and every element of the claimed invention, particularly not as arranged in the claim. As stated above, the property of drought tolerance is a product of at least the components of the vector construct (including the nucleotide sequence that encodes the DRO2 polypeptide and the heterologous constitutive promoter) utilized by Applicants to transform the transgenic plant. Again, the sequence alone is not sufficient to result in a transgenic plant as presently claimed (as demonstrated by Harper *et al.*). Nowhere do Harper *et al.* disclose the specific

combination of a heterologous constitutive promoter and the nucleotide sequence that encodes the DRO2 polypeptide as presently required in the pending claims. Therefore, the teachings of Harper *et al.* are insufficient to establish anticipation because each and every element of the claimed invention are not disclose as arranged in the presented claims.

Applicants also remind the Office that "[A]nticipation by inherent disclosure is appropriate only when the reference discloses prior art that must *necessarily* include the unstated limitation" (*Transclean Corp. v. Bridgewood Services, Inc.*, 290 F.3d 1364, 1373, 62 USPQ2d 1865, 1871 (Fed. Cir. 2002); emphasis in original). Moreover, "[I]n relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic *necessarily* flows from the teachings of the applied prior art" (*Ex parte* Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Int'f 1990); emphasis in original). "Inherency . . . *may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient*" (*In re* Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999); emphasis added).

As the present rejection is one of inherent anticipation, the Examiner must show that Harper *et al.* *necessarily* teaches a transgenic plant with drought tolerance including a vector construct (including the nucleotide sequence that encodes the DRO2 polypeptide linked to a heterologous constitutive promoter) or a method of making a plant thereof as recited in the pending claims. Here, the Examiner's statement that the data provided by Harper *et al.* "does not provide evidence against the drought tolerant property of the product" (Office action, page 8) is clearly a statement of possibility and does not "provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic *necessarily* flows from the teachings of the applied prior art." Not all transgenic plants expressing the nucleotide sequence that encodes the DRO2 polypeptide exhibit drought tolerance (as demonstrated by Harper *et al.* themselves). In this regard, the drought tolerance is not *necessarily* a consequence of expression of a nucleotide sequence encoding SEQ ID NO:2. Thus, Applicants submit that claims 1, 5-8, 10 and 16 are not inherently anticipated by Harper *et al.*

Anticipation (including inherent anticipation) of the current claims has not been established. As such, Applicants respectfully request that the rejections under 35 U.S.C. §102(e) be withdrawn with regard to the claims currently pending in this case.

Newly Added Claims (Claims 20-22)

Newly added claims 20-22 are believed to be allowable as being free of the cited art and satisfying all conditions for patentability. These claims are believed to be in accordance with suggestions provided by Examiner Kumar.

Conclusion

Applicants respectfully submit that the claims submitted herewith are in condition for allowance. If any issues impede the issuance of a notice of allowance, Applicants expressly request that the Examiner contact the undersigned prior to the mailing of an Advisory Office action in order to arrange a telephone interview. It is believed that a brief discussion of the merits of the present application may expedite prosecution and allowance of the claims.

Respectfully submitted,

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